DESTINATION STARTUP

Microbial Pulse Diagnostics

One-Sentence Summary of What You Do: Microbial Pulse Diagnostics (MPD) will enable point-of-care data-driven antibiotic prescriptions by providing physicians with a list of proven effective drugs in under two hours. Our nanoscale sensing technology "takes the pulse" of the bacteria causing a urinary tract infection to quickly determine their phenotypic susceptibility or resistance to antibiotics.

Affiliated Institution: NIST

Have you formed a company yet? Yes

Funding/Financing: Grant Funding

Please describe your company and the problem you are trying to solve: What was once an easily solved problem — picking an antibiotic to treat a urinary tract infection (UTI) — is now at the source of >375,000 serious cases of sepsis and 62,000 deaths in the US each year as rising antimicrobial resistance renders physicians' best-guess treatment strategies ineffective. Physicians need faster testing to be able to treat with the best narrow- spectrum, safe antibiotic available for their patient's specific infection.

Our core innovation is the measurement of biophysical activity of bacteria with such sensitivity that the loss of cellular viability after antibiotic exposure is detected in real time. Microbes coupled to the surface of a piezoelectric crystal introduce phase noise to its resonance signal; our system senses drops in noise as cells respond to a drug.

By delivering phenotypic susceptibility in under two hours, Microbial Pulse Diagnostics' (MPD) rapid biophysical diagnostic gives physicians the information they need to treat UTIs correctly at the first point of care. For patients this means faster UTI cures, lower chance of developing resistant infections, and better protection of their native protective microbial flora (i.e., gut microbiome). For physicians, this means they can diagnose more quickly and deliver more effective care without having to change prescriptions. Depending on the healthcare setting (e.g., primary care practices), it can also allow physicians to own in-house susceptibility testing.

What is/was your go-to-market strategy? The most common tests for infectious disease susceptibility today are based on selective growth of pathogens from clinical samples, which requires two full days to identify organisms and test susceptibility. Our test is much faster (< two hours). Reflecting the enormous potential impact, ours is not the only approach being pursued to deliver faster AST. But, because our biophysical approach is fundamentally different from other techniques using a chemical/molecular (DNA-based) readout and/or requiring significant cell growth, we are offering a unique combination of speed and phenotypic testing.

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How will/do you generate revenue? The MPD product has two parts: 1) An electronic readout instrument and 2) A disposable cassette holding 8-16 resonating sensors. A urine sample collected at point-of-care will flow across all resonators in parallel, with each one testing response to a different antibiotic, delivering a binary susceptible or resistance result. All fluid handling and data interpretation will be on board, requiring minimal technician or nurse interaction. Physicians are delivered a menu of susceptible antibiotic options to guide their prescription.

Following FDA clearance, we plan to sell disposable resonator cassettes for each patient test, targeting under $200 per test. Instruments will be placed through a variety of mechanisms, but we expect to need to provide instruments under no-cost fixed term (e.g., five years) contracts for consumables.

How will this showcase benefit your company or technology? MPD has (1) an alpha prototype instrument which has (2) collected first clinical data showing accurate testing for susceptibility of pathogens isolated directly from patient UTI samples. Prototyping of the disposable resonator cassette (3) is underway and nearing completion. When starting MPD, we identified these three technical milestones as priorities to be met before finding sources of dilutive funding.

We have an NSF SBIR Phase I grant and will be applying for Phase II in February 2020. We are now seeking $500k in bridge funding for the gap after Phase I while our Phase II proposal is reviewed. This showcase will help MPD gain a wider introduction to the Colorado biotech and investment communities at an opportune time.

Who are the members of your team and why is this the right team to get the job done?

- Danielle France, PhD, CEO, co-founder, principal investigator — Danielle holds a doctorate in biological engineering from MIT, and has over 15 years of experience in biophysics and microbiology research. As PI for the Microbial Pulse project at NIST, she brought in the first $250K in seed funding from NIST's Material Measurement Laboratory Angel Investor Competition. She maintains her hands- on expertise in wet labs as well as in data acquisition and analysis in order to drive technology development.
- Fred Walls, PhD, CTO, co-founder, co-investigator — Fred holds a doctorate in physics from the University of Washington, and has had a long career in analog electronics, primarily at NIST leading a Phase Noise research group within the Time and Frequency Division. He has over 197 publications and seven patents. He built the proof-of-concept measurement platform for the Microbial Pulse project at NIST, and continues with hands-on electronic prototype development as MPD CTO.
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The MPD team is truly multidisciplinary, with expertise needed to span clinical microbiology to resonator physics, microfluidics, and electronics design, spearheaded by a biological engineer with the background to translate between fields.

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Other team members include Ian Babson, Microbiologist (full-time), Jenifer Blacklock, PhD, Mechanical Engineer (part-time), Shelley Kon, MD, Infectious Disease Fellow (part-time), Connie Price, MD, Denver Health Chief Medical Officer (advisor), John Miles, digital embedded systems expert (subcontractor).

In the very near future, the MPD team would like to add an executive for general business development, and a second engineer for prototyping and design work.